Case **MPSCO-007A**

BLOOD DRAWING SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS
(Not Applicable)

STATEMENT RE: FEDERALLY SPONSORED RESEARCH/DEVELOPMENT
(Not Applicable)

BACKGROUND OF THE INVENTION

[0001] The present invention relates in general to blood drawing systems, and in particular to a blood drawing system which, in one embodiment, permits negative pressure control within a vessel to which blood is drawn for preventing vessel collapse because of excess pressure, and, in a second embodiment, for removing and conserving for re-introduction medicament liquid fed through an intravenous conduit prior to blood withdrawal through the intravenous conduit to a negative-pressure collection vessel.

[0002] Employment of negative-pressure vessels for collecting blood samples from arterial or venous blood vessels of living beings is a common practice in medical treatments where subsequent laboratory analysis of the blood samples so collected helps in diagnosing and treating illnesses. In those who are relatively healthy, the use of standard negative-pressure collection vessels, as exemplified by VACUTAINER brand tubes manufactured by Becton Dickinson, provide excellent withdrawal properties without causing vessel collapse. However, in patients whose vascular system is fragile, the negative pressure within a vacuum tube can be excessive, and such excessive negative pressure can cause vessel collapse as suction from

the vacuum tube attempts to extract a blood sample.

[0003] At the present time, phlebotomists overcome this problem by drawing the blood sample into a standard syringe where negative pressure application can be controlled by the speed at which the plunger of the syringe is withdrawn. In this manner blood can be withdrawn slowly and without vessel collapse. However, the blood so drawn into a syringe then must be transferred to a vacuum tube because of required anticoagulant and/or other blood-preservation additives present in the vacuum tube. Such transfer can only be accomplished by attaching a standard hollow needle to the syringe, piercing the stopper can of the vacuum tube, and expelling the syringe content into the vacuum tube. As is recognized to those with ordinary skill in the art, the above-described attachment of the needle to the syringe is potentially a very dangerous event because an easily-occurring finger-stick of the technician performing the task can mean the transfer of patient blood to the technician along with blood-borne disease. Therefore, a primary object of the present invention is to permit blood transfer from a drawing syringe to a negative-pressure collection vessel through a closed network not requiring attachment of a needle to the syringe.

[0004] A second situation where blood-sample withdrawal is required is in connection with a typical intravenous drip line having a port to which a negative-pressure collection vessel (e.g. a vacuum tube) can be connected for easy blood withdrawal through the line. As is evident, however, if the line is not first cleared of drip-liquid, any blood sample will have a high amount of such medicament liquid and therefore will not provide a true blood-only sample. This problem presently is addressed by turning off the drip from its source and thereafter withdrawing and discarding all fluid from the drip line prior to opening the port to the vacuum tube. As is evident, this approach

not only decreases (and wastes) the intended drip-liquid amount for the patient, but also causes loss of at least a small amount of blood from the patient as the drip line is filled with only blood for vacuum tube collection. One or both of these disadvantages can be harmful to a patient. In particular, if the amount of drip-liquid to be delivered to a patient is critical, such amount is automatically compromised with drip-liquid loss. Second, if the patient is a neonatal child with a corresponding very low volume of blood, even a small blood loss which occurs during each drip line clearance can create a dangerous health hazard. Consequently, a second object of the present invention is to provide a closed drip-line system in which medicament liquid cleared from the drip line prior to blood withdrawal into the vacuum tube is collected for reintroduction after the blood sample has been drawn. In this manner, both drip-liquid and blood volume are conserved for the patient.

[0005] These and other objects of the present invention will become apparent throughout the description thereof which now follows.

BRIEF SUMMARY OF THE INVENTION

[0006] The present invention first provides a blood drawing system for drawing blood from a blood vessel of a living being. This system comprises a selectively-closeable first conduit through which blood drawn from a blood vessel can flow; a first collection vessel for receiving blood and having an exteriorly-operable pressure controller for application of negative or positive pressure therein; a hollow-shaft member; a second conduit having a first end in fluid communication with the first conduit and a second end in fluid communication with the first collection vessel; and a third conduit having a first end in communication with the first conduit and a second end in communication with the hollow shaft member. In operation,

a negative pressure second collection vessel is connected in fluid communication with the hollow shaft member. Thereafter, the closing of the first conduit allows medicament liquid transfer from the first collection vessel through the hollow shaft member and into the second collection vessel upon positive pressure application with the pressure controller within the first collection vessel without exposure to or inclusion of any external devices to accomplish such transfer. In a preferred embodiment, the first collection vessel is a standard syringe with a plunger therein, the hollow shaft member is a needle, and the second collection vessel is a standard vacuum tube with a needle-penetrable stopper which is so penetrated by the hollow shaft member.

[0007] The present invention further provides an intravenous system for delivering a medicament liquid to a blood vessel and for collecting blood from the blood vessel through the system, yet substantially free of the medicament liquid. The system comprises a vascular first conduit having a first end thereof for liquid communication with a storage container for storing the medicament liquid and a second end thereof for liquid communication with the blood vessel; a first collection vessel for receiving blood and having an exteriorly-operable pressure controller for application of negative or positive pressure within the first collection vessel; a hollow shaft member; a selectively closeable second conduit having a first end in fluid communication with the first conduit and a second end in fluid communication with the first collection vessel; and a selectively closeable third conduit having a first end in fluid communication with the first conduit and a second end in fluid communication with the hollow shaft member. In operation, a negative pressure second collection vessel is connected in fluid communication with the hollow shaft member. Thereafter, closing the third

conduit, opening the second conduit, and applying negative pressure to the first collection vessel collects in the first collection vessel at least substantially all medicament liquid present within the first conduit, and thereafter closing the second conduit and opening the third conduit directs substantially medicament liquid-free blood resultantly present within the first conduit through the third conduit and the hollow shaft member into the second collection vessel.

[0008] As is thus apparent, the present invention accomplishes blood transfer from a drawing syringe to a negative-pressure collection vessel through a closed network not requiring attachment of a needle to the syringe, and additionally accomplishes a closed drip-line system in which medicament liquid cleared from the drip line prior to blood withdrawal is conservedly collected for reintroduction after the blood sample has been drawn.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] An illustrative and presently preferred embodiment of the invention is shown in the accompanying drawings in which:

[0010] Figure 1 is a perspective view of a blood drawing system showing an open clamp on a blood-transfer conduit;

[0011] Figure 2 is a perspective view of the blood drawing system of Figure 1 showing a closed clamp;

[0012] Figure 3 is a perspective view of an intravenous system for delivering a medicament liquid to a blood vessel and for collecting blood through the system, showing one clamp thereof open and one clamp thereof closed; and

[0013] Figure 4 is a perspective view of the intravenous system of Figure 3 with clamp positions reversed.

DETAILED DESCRIPTION OF THE INVENTION

Sub. A6.

[0014] Referring first to Figures 1 and 2, a blood

drawing system 10 is shown. The system 10 includes a first conduit 12 through which blood from a blood vessel (not shown) of a patient can flow upon standard needle entry thereto. The first conduit 12 is provided with a closure member here non-limitedly shown as a sliding clamp 14, with Figure 1 showing the clamp 14 in an open position and Figure 2 showing it in a closed position. A standard syringe 16 functions as a first collection vessel for receiving blood, and has a standard exteriorly-operable plunger 18 for controllably applying negative or positive pressure within the syringe 16. A second conduit 20 has a first end thereof in fluid communication with the first conduit 12 and a second end thereof in fluid communication with the syringe 16. The system 10 includes a hollow-shaft member here non-limitedly exemplified as a hollow needle 22 and a third conduit 24 having a first end thereof in fluid communication with the first conduit 12 and a second end thereof in fluid communication with the needle 24. Preferred operation includes a fluid communication of the needle 24 with a standard vacuum tube such as a VACUTAINER brand tube as earlier identified (not shown) through a needle-penetrable stopper, with the tube conventionally retained in a tube holder 26 as known in the art. As is apparent, closing the first conduit 12 allows medicament liquid transfer from the syringe 16 through the needle 22 upon positive pressure application with the plunger 18.

[0015] In operation, the first conduit 12 is connected to a catheter (not shown) leading from a blood vessel of the patient such that blood can flow into the first conduit 12. The clamp 14 is open (Figure 1) and an operator withdraws the plunger 18 of the syringe 16 to create negative pressure and cause blood entry into the syringe 16. After such blood-sample collection is complete, plunger activity is ceased and the clamp 14 is closed (Figure 2). A vacuum tube is fixed in fluid connection

with the needle 22 and the blood from the syringe 16 is moved therefrom by positive pressure created by inward operator movement of the plunger 18. The blood from the syringe 16 first travels through the second conduit 20 into the first conduit 12 to the site of the clamp 14, and then returns into the third conduit 24 for continued travel through the hollow needle 22 and into the vacuum tube. Typically, the vacuum tube will have an anticoagulant therein which preserves the blood sample in analytical condition for a sufficient amount of time such that laboratory procedures can be completed. To this end, the vacuum tube is withdrawn from the holder 26 for such laboratory delivery.

Sub. A7.

[0016] Referring now to Figures 3 and 4, an intravenous system 40 for delivering a medicament liquid to a blood vessel (not shown) and for collecting blood from the blood vessel through the same system 40 is illustrated. In particular, the system includes a connecting vascular first conduit 42 having a first end 44 for receiving medicament liquid as from a standard IV drip bag 50 and a second end 46 thereof for fluid communication via a standard catheter (not shown) or the like with the blood vessel. The first conduit 42 is provided with a closure member here non-limitedly shown as a sliding clamp 14a, with Figure 3 showing the clamp 14a in a closed position and Figure 4 showing it in an open position. A standard syringe 16 functions as a first collection vessel, and has a standard exteriorly-operable plunger 18 for controllably applying negative or positive pressure within the syringe 16. A second conduit 48 has a first end thereof in fluid communication with the first conduit 42 and a second end thereof in fluid communication with the syringe 16, and is provided with a sliding clamp 14b shown in an open position in Figure 3 and a closed position in Figure 4. The system 40 includes a hollow-shaft member here non-limitedly

exemplified as a hollow needle 22 and a third conduit 52 having a first end thereof in fluid communication with the first conduit 42 and a second end thereof in fluid communication with the needle 24. Preferred operation includes a fluid communication of the needle 24 with a standard vacuum tube such as a VACUTAINER brand tube as earlier identified (not shown) through a needle-penetrable stopper, with the tube conventionally retained in a tube holder 26 as known in the art. As is apparent, closing the first conduit 42 with the clamp 14a prohibits fluid movement upstream from the second conduit 48, while closure of the second conduit 48 with the clamp 14b prohibits fluid movement through the second conduit 48.

[0017] In operation during traditional medicament liquid delivery from the drip bag 50 to a blood vessel, most commonly a vein, of a patient, the first conduit 42 is connected at its first end to the drip bag 50 and at its second end to a catheter or the like (not shown) leading to the blood vessel. The clamp 14a is in the open position while the clamp 14b is in the closed position, thereby permitting medicament liquid flow into the blood vessel. When a blood sample is needed during such medicament liquid delivery and is to be withdrawn through the first conduit 42, an operator first closes the clamp 14a to thereby stop medicament liquid flow from the drip bag 50. Since the first conduit 42 still contains medicament liquid downstream from the clamp 14a and therefore can not yield a generally medicament liquid-free blood sample if drawn through the first conduit 42, it is necessary to remove such medicament liquid prior to blood-sample withdrawal. Such medicament liquid removal is accomplished by opening the clamp 14b of the second conduit 48 and withdrawing the plunger 18 of the syringe 16 to create negative pressure within the syringe 16 and draw the medicament liquid still in the first conduit 42. Such medicament liquid withdrawal

is continued until blood becomes present within the syringe, at which time the clamp 14b is closed. A vacuum tube is fixed in fluid connection with the needle 22 and the clamp 14a of the first conduit is then opened to permit the substantially medicament liquid-free blood now present in the first conduit 42 to travel through the hollow needle 22 into the vacuum tube. Once this blood sample is collected in the vacuum tube, the vacuum tube is withdrawn from the holder 26, the clamp 14a is closed, the clamp 14b is opened, and the medicament liquid and blood present in the syringe 16 is forced by inward movement of the plunger 18 back through the second conduit 48 into the first conduit 42 for return to the patient while the clamp 14a is again opened to permit medicament liquid flow from the drip bag 50 through the first conduit 42 and into the blood vessel. In this manner, a closed drip-line system is provided in which medicament liquid cleared from the first conduit 42 prior to blood withdrawal is conservedly collected and thereafter returned to the patient after the blood sample has been drawn.

[0018] While illustrative and presently preferred embodiments of the invention have been described in detail herein, it is to be understood that the inventive concepts may be otherwise variously embodied and employed and that the appended claims are intended to be construed to include such variations except insofar as limited by prior art.